DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 15 2003

Douglas L. Sporn
Divisional VP, Regulatory Affairs
Global Pharmaceutical Research and Development
Abbott Laboratories
100 Abbott Park Rd.
Abbott Park, IL 60064-6091

Re: IND 62,720 (Synthroid)

Dear Mr. Sporn:

This responds to your formal dispute resolution request and, in particular, your letter dated April 14, 2003 and received April 15, 2003. Your request relates to the appropriate study method for sponsors seeking to show bioequivalence and therapeutic equivalence of oral levothyroxine sodium drug products.

The issues you raise regarding the methods for showing bioequivalence and therapeutic equivalence of levothyroxine sodium products are not limited to Synthroid but are of significant interest to other manufacturers of levothyroxine sodium, including generic drug applicants. Although Abbott Laboratories (Abbott) may be affected by the outcome of any Agency decision on these issues, other interested parties may also be affected. As I am sure you know, Jones Pharma, Inc., submitted a citizen petition dated March 28, 2003, on the very matter covered by your request. *See* Docket No. 03P-0126. Accordingly, we believe it is most appropriate to consider the issues raised in your request in a public manner. This approach will allow others the opportunity to comment and participate in the decision-making process, will provide Abbott the opportunity to comment publicly on the views and opinions of others, and will establish an administrative record on which the Agency may base any future decisions.

We acknowledge that in a letter dated January 14, 2003, Dr. David Orloff, Director, Division of Metabolic and Endocrine Drug Products, Center for Drug Evaluation and Research (CDER), noted that you could request reconsideration of the Division's decision through CDER's dispute resolution process. At that time, you had raised the bioequivalence and therapeutic equivalence issues, including the submission of results for Study M02-417, in Abbott's IND for Synthroid. As your dispute resolution has progressed, it has become clear that, for the reasons described above, this matter would be more appropriately resolved in a public forum.

IND 62,720 (Synthroid)

We request, therefore, that you submit the concerns expressed in your formal dispute resolution request as a comment to Docket No. 03P-0126, or, if you prefer, as a separate citizen petition under 21 CFR §10.30.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research